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09/762,277	02/06/2001	Takaki Waritani	2000_1588A	3690

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EXAMINER
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GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/762,277**

Applicant(s)  
**WARITANI et al.**

Examiner  
**James L. Grun, Ph.D.**

Art Unit  
**1641**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other: \_\_\_\_\_

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The disclosure is objected to because of the following informalities: the specification is replete with grammatical, idiomatic, and spelling errors and should be carefully revised. Appropriate  
5 correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10 Claims 1-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 are vague and indefinite as to what is intended as encompassed because the metes and bounds of “trypsin-related” and/or “trypsin-like” cannot be determined.

15 In claims 3 and 5, “the Sequence Listing” lacks antecedent basis and the recitation thereof in the body of the claims in addition to “SEQ ID NO:” identifiers is superfluous.

Claims 6 and 7 provide for the use of the monoclonal antibody of claim 1, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process

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applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

In claims 8 and 9, "a" monoclonal antibody should be "the" monoclonal antibody for proper antecedent support. In these claims it is not clear for what the amount is "effective" because no function to be performed is recited in the body of the claims, therefore it is unclear what an "effective" amount comprises. It is not clear what, if anything other than intended use, is being further limited in claim 8 by the elements of claim 9.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6 and 7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5        Claims 1-9 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hermon-Taylor et al. (U.S. Pat. No. 5,356,781) in light of the instant disclosure.

Hermon-Taylor et al. disclose antibodies, polyclonal or monoclonal, to a peptide derived from trypsinogen, as also found in both anionic and cationic canine trypsinogen in light of the instant disclosure, for detection of pancreatic disease, and teach the inclusion of the antibodies in reagents and kits for performing assays for the detection.

10        Claims 1-3 and 5-9 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Guy-Crotte et al. (Eur. J. Biochem 204: 133, 1992).

15        Guy-Crotte et al. disclose the G6 monoclonal antibody which binds to dog trypsinogen, however it was not determined if the antibody bound anionic, cationic or both dog trypsinogens (see page 136, col. 1). The antibody reagent was used in immunoassays to detect the protein (see page 135, col. 2, text and Fig. 4B).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

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5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

15 Claims 1-5, 8, and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pinsky et al. (Mol. Cell. Biol. 5(10): 2669, 1985) in view of Campbell (1984), Harlow et al, and Maurer et al.

Pinsky et al. cloned the two major forms of canine trypsinogen and teach the sequences thereof. In contrast to the invention as instantly claimed, the reference does not specifically teach  
20 antibodies to the proteins.

Campbell teaches (page 29) that affinity purification uses of monoclonal antibodies are known to the art and that "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)."

25 Harlow et al. teach that, once the amino acid and/or nucleic acid sequences of a protein are known, it is routine and conventional in the art to elicit antibodies to peptides and/or fusion proteins

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derived from the protein and/or to prepare a bank of site-specific monoclonal antibodies for a variety of uses such as functional and clinical studies (pages 72-77). Harlow et al further teach rationales for the selection of synthetic peptides as immunogens (pages 72-77).

5 Maurer et al. teach that the method by which a protein or polypeptide immunogen is presented to a host can influence the ability of that immunogen preparation to elicit a response, i.e. by employing the correct "carrier" and conjugation procedure for a protein or polypeptide, an immune response to almost any macromolecule (even those believed to be nonimmunogenic) can be elicited (page 50). Further, the reference teaches typical methods for the production of both polyclonal and monoclonal antibodies (pages 64-67).

10 It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have elicited antibodies to any peptide epitope of a canine trypsinogen protein sequence as disclosed by Pinsky et al. because the canine trypsinogen proteins are of unquestioned research interest, its is conventional in the art to elicit antibodies to sequenced proteins for a variety of uses as taught in either of Campbell or Harlow et al., and one of ordinary skill in the art would have had  
15 an extremely reasonable expectation of success in achieving the expected result, i.e. generating antibodies, either polyclonal or monoclonal antibodies specifically reactive with specific peptide epitopes in canine trypsinogen proteins, using synthetic peptide immunogens derived from the sequences of the canine trypsinogen proteins, taught in Pinsky et al., in conjunction with notoriously old and well known conventional techniques as taught by Harlow et al. and Maurer et al. See Ex  
20 parte Erlich (3 USPQ2d 1011 (BPAI 1987)). It would have been obvious to have generated

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monoclonal antibodies in order to provide a potentially unlimited source of homogeneous reagent for uses such as affinity purification, functional studies, or clinical studies of the proteins. It would have been obvious to have provided any of the conventional detectable labels on the antibodies as such labelling is conventional in the art for, inter alia, detection of antibody binding. It would have  
5 been further obvious to formulate the reagents of Pinsky et al., as modified, into a kit since that is conventional for convenience, economy, and reproducibility.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinsky et al.,  
10 Campbell (1984), Harlow et al., and Maurer et al. as applied to claims 1-5, 8, and 9 above, and further in view of Campbell (1991) and either of Simpson et al. (Am. J. Vet. Res. 50(5): 629, 1989) or Borgström et al (Hoppe-Seyler's Z. Physiol. Chem. 361: 625, 1980).

The teachings of Pinsky et al., Campbell (1984), Harlow et al., and Maurer et al. are as set forth previously and differ from the invention as instantly claimed in not specifically teaching an  
15 immunoassay for determination of canine trypsinogen proteins.

Either of Simpson et al. or Borgström et al. teach immunoassays of canine trypsinogens for determination of pancreatitis.



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Campbell (1991) teaches the general procedure for the production of monoclonal antibodies (pages 3-6) and that substituting a monoclonal antibody for a polyclonal antibody in an established immunoassay "is not novel and is obvious" (page 45).

5 It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have substituted the monoclonal antibodies taught by the combination of Pinsky et al. with Campbell (1984), Harlow et al., and Maurer et al. in the immunoassays of either of Simpson et al. or Borgström et al. because Campbell (1991) teaches that such a substitution is obvious to one of ordinary skill in the art. One would have had obvious motivation to have substituted monoclonal antibodies in order to make use of a potentially unlimited source of homogeneous reagent to  
10 standardize the assay.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

The EP patent (EP 1,106,701 A1) corresponding to the instant disclosure is noted.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.



James L. Grun, Ph.D.  
June 23, 2003



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